

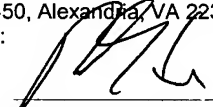
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October 22, 2003

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Date	Robert E. Hanson

**MS DD**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

RE: *U.S. Patent Application No. 10/655,547 entitled "COMPOSITIONS AND METHODS FOR EARLY PREGNANCY DIAGNOSIS" – Robert Michael Roberts et al.*  
*Our reference: UVMO:003USC1*

Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement and Form PTO-1449.

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/UVMO:003USC1.

Please date stamp and return the enclosed postcard evidencing receipt of these materials.

Respectfully submitted,



Robert E. Hanson  
Reg. No. 42,628

REH/kmv  
Encl.: as noted

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**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  
Robert Michael Roberts *et al.*

Serial No.: 10/655,547

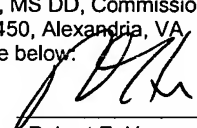
Filed: September 4, 2003

For: COMPOSITIONS AND METHODS FOR  
EARLY PREGNANCY DIAGNOSIS

Group Art Unit: Unknown

Examiner: Unknown

Atty. Dkt. No.: UVMO:003USC1

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Date	Robert E. Hanson

**INFORMATION DISCLOSURE STATEMENT**

**MS DD**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be

an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/UVMO:003USC1.

This application is a continuation application of Serial No. 09/273,164, filed March 19, 1999 which claims priority to provisional application 60/078,783 filed March 20, 1998 and provisional application 60/106,188 filed October 28, 1998 and is relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with Rule 37 C.F.R. § 1.98(d) copies of the listed documents are not enclosed as they have been previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. 09/273,164.

Applicants respectfully request that the listed documents be made of record in the present case.

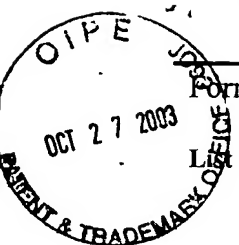
Respectfully submitted,



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Date: October 22, 2003



Form PTO-1449 (modified)

List of Patents and Publications for Applicant's

## INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. D cket No.

UVMO:003USC1

Serial No.

10/655,547

Applicant

Robert Michael Roberts *et al.*

Filing Date:

September 4, 2003

Group:

Unknown

U.S. Patent Documents

See Page 1

Foreign Patent Documents

See Page 1

Other Art

See Page 1

## U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	2001/0024799	09/27/01	Jordan <i>et al.</i>	435	7.9	01/17/01
	A2	4,271,140	07/02/81	Bunting	436	500	08/01/78
	A3	4,895,804	01/23/90	Bostwick <i>et al.</i>	435	240.27	08/24/87

## Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	99/06038	02/19/99	PCT			

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

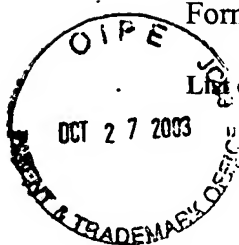
Exam. Init.	Ref. Des.	Citation
	C1	Atkinson <i>et al.</i> , "Characterization of placentation-specific binucleate cell glycoproteins possessing a novel carbohydrate," <i>J. Biol. Chem.</i> , 268(35:26679-26685, 1993.
	C2	Birch and Loh, "Homology cloning of aspartic preteases from an endocrine cell line using the polymerase chain reaction," <i>Biochem. Biophys. Res. Commun.</i> , 177(3):920-926, 1993.
	C3	Cameron and Malmo, "Evaluation of an ultrasonic doppler probe for pregnancy diagnosis in cattle," <i>Austr. Vet. J.</i> , 70:109-111, 1993.
	C4	Davies, "The structure and function of the aspartic proteinases," <i>Ann. Rev. Biophys. Chem.</i> , 19:189-215, 1990.
	C5	Garabayo <i>et al.</i> , "Caprine pregnancy-associated glycoproteins (PAG): Their cloning expression and evolutionary relationship to other PAG," <i>Mo. Reprod Dev</i> , 57:311-322, 2000.
	C6	Gerrie <i>et al.</i> , "Pregnancy-associated alpha-2 glycoprotein: development of a sensitive enzyme-linked immunoassay and comparison of serum concentrations in adults and children," <i>Clinical Chimica. Acta</i> , 155:51-60, 1986.
	C7	Green <i>et al.</i> , "Bovine pregnancy-associated glycoproteins (PAG) exhibit distinct expression patterns during gestation," <i>Biol Reprod</i> , 60(Suppl 1):497, 1999.

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Form PTO-1449 (modified)

List of Patents and Publications for Applicant's

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. Docket No.

UVMO:003USC1

Serial No.

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Applicant

Robert Michael Roberts *et al.*

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U.S. Patent Documents

See Page 1

Foreign Patent Documents

See Page 1

Other Art

See Page 1

**Other Art (Including Author, Title, Date Pertinent Pages, Etc.)**

Exam. Init.	Ref. Des.	Citation
	C8	Green <i>et al.</i> , "Identification of a family of Kunitz domain proteins expressed in bovine and ovine trophoblast," <i>Biol Reprod</i> , 58 (Suppl 1):310.
	C9	Green <i>et al.</i> , "Identification of a new aspartic proteinase expressed by the outer chorionic cell layer of the equine placenta," <i>Biol. Reprod.</i> , 60:1069-1077, 1999.
	C10	Green <i>et al.</i> , "Pregnancy-associated bovine and ovine glycoproteins exhibit spatially and temporally distinct expression patterns during pregnancy," <i>Biol. of Repro.</i> , 62:1624-1631, 2000.
	C11	Green <i>et al.</i> , "Pregnancy-associated glycoproteins of the horse," <i>Biol Reprod</i> , 50 (Suppl 1):152, 1994.
	C12	Green <i>et al.</i> , "Pregnancy-associated glycoproteins: A family of catalytically inactive aspartic proteinases," <i>Mol Biol Cell</i> , 6 (Suppl 1):454, 1995.
	C13	Green <i>et al.</i> , "The establishment for an ELISA for the detection of pregnancy-associated glycoproteins (PAGs) in the serum of pregnant cows and heifers," Departments of Animal Sciences and Biochemistry, University of Missouri-Columbia.
	C14	Guillomot, "Cellular interactions during implantation in domestic ruminants," <i>J. Reprod. Fertil.</i> , 49(Suppl.):39-51, 1995.
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	C16	Haig, "Genetic conflicts in human pregnancy," <i>Rev. Biol.</i> , 68:495-532, 1993.
	C17	Hughes <i>et al.</i> , "Adaptive diversification within a large family of recently duplicated, placentally expressed genes," <i>Proc. Natl. Acad. Sci., USA</i> , 97:3319-3323, 2000.
	C18	Inoue <i>et al.</i> , "Aspergillus niger var. Macrosporus proteinase B. cDNA cloning, expression, and activation of the proteinases, <i>Aspartic Proteinases</i> , 581-587, 1995.
	C19	Ishiwata <i>et al.</i> , "Characterization of gene expression profiles in early bovine pregnancy using a custom cDNA microarray," <i>Mol Reprod Dev.</i> , 65(1):9-18, 2003.
	C20	King <i>et al.</i> , "Development of the bovine placenta from days 20 to 29 of gestation," <i>J. Reprod. Fert.</i> , 59:95-100, 1980.

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Form PTO-1449 (modified)		Atty. Docket No. UVMO:003USC1	Serial No. 10/655,547
List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)		Applicant Robert Michael Roberts <i>et al.</i>	
		Filing Date: September 4, 2003	Group: Unknown
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 1</i>	

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C21	Kiracofe <i>et al.</i> , "Pregnancy-specific protein B in serum of postpartum beef cows," <i>J. Anim. Sci.</i> , 71:2199-2205, 1993.
	C22	Li <i>et al.</i> , "Mutational analysis of the vesicular stomatitis virus glycoprotein G for membrane fusion domains," <i>J. Virol.</i> , 67(7):4070-4077, 1993/
	C23	Mialon <i>et al.</i> , "Detection of pregnancy by radioimmunoassay of a pregnancy serum protein (PSP60) in cattle," <i>Reprod. Nutr. Dev.</i> , 34:65-72, 1994.
	C24	Mialon <i>et al.</i> , "Peripheral concentrations of a 60-kDa pregnancy serum protein during gestation and after calving and in relationship to embryonic mortality in cattle," <i>Reprod. Nutr. Dev.</i> , 33:269-282, 1993.
	C25	Patel <i>et al.</i> , "Effect of fetal mass, number, and stage of gestation on pregnancy-specific protein B concentrations in the bovine," <i>Theriogenol.</i> , 44:827-833, 1995.
	C26	Patel <i>et al.</i> , "Plasma bovine pregnancy-associated glycoprotein concentrations throughout gestation in relationship to fetal number in the cow," <i>Eur. J. Endoc.</i> , 137:423-428, 1997.
	C27	Roberts <i>et al.</i> , "Glycoproteins of the aspartyl proteinase gene family secreted by the developing placenta," <i>Aspartic Prot., Struct., Funct., Biol., Biom., Impl.</i> , 231-240, 1995.
	C28	Roberts <i>et al.</i> , "Maternal Recognition of pregnancy," <i>Biol. Reprod.</i> , 54:294-302, 1996.
	C29	Roberts <i>et al.</i> , "New and atypical families of type I interferons in mammals: comparative functions, structures, and evolutionary relationships," <i>Prog. Nucl. Acid Res. Mol. Biol.</i> , 56:287-326, 1997.
	C30	Sasser <i>et al.</i> , "Characterizations of pregnancy-specific protein B in cattle," <i>J. Reprod. Fertil.</i> , 37(suppl.):109-113, 1989.
	C31	Sasser <i>et al.</i> , "Detection of pregnancy by radioimmunoassay of a novel pregnancy-specific protein in serum of cows and a profile of serum concentrations during gestation," <i>Biol. Reprod.</i> , 35:936-942, 1986.
	C32	Scott <i>et al.</i> , "Serum levels of pregnancy-associated alpha2-glycoprotein during pregnancy in autoimmune thyroid disease: relationship to disease activity," <i>Clinical and Experimental Immunology</i> , 59:564-570, 1985.
	C33	Szafranska <i>et al.</i> , "Porcine pregnancy-associated glycoproteins: new members of the aspartic proteinase gene family expressed in trophectoderm," <i>Biol. Reprod.</i> , 53:21-28, 1995.

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	C34	Szafranska <i>et al.</i> , "The genes for porcine and bovine pregnancy-associated glycoprotein 2: Its structural organization and analysis of its promoter," <i>Mol. Reprod. Dev.</i> , 66:137-146, 2001.
	C35	Szenci <i>et al.</i> , "Evaluation of false ultrasonographic diagnoses in cows by measuring plasma levels of bovine pregnancy-associated glycoprotein 1," <i>Vet. Record</i> , 304-306, 1998.
	C36	Wedemayer, "Structural insights into the evolution of an antibody combining site," <i>Science</i> , 276(5319):1665-1669, 1997.
	C37	Wooding, "Current topic: the syneptitheliochorial placenta of ruminants: binucleate cell fusions and hormone production," <i>Placenta</i> , 13:101-113, 1992.
	C38	Xie <i>et al.</i> , "A novel glycoprotein of the aspartic proteinase gen family expressid in bovine placental trophoctoderm," <i>Biol. Reprod.</i> , 51:1145-1153, 1994.
	C39	Xie <i>et al.</i> , "Identification of the major pregnancy-specific antigens of cattle and sheep as inactive members of the aspartic proteinase family," <i>Proc. Natl. Acad. Sci., USA</i> , 88:10247-10251, 1991.
	C40	Xie <i>et al.</i> , "Multiple pregnancy-associated glycoproteins are sevreted by day 100 ovine placental tissue," <i>Biol. Reprod.</i> , 57:1384-1393, 1997.
	C41	Xie <i>et al.</i> , "The diversity and evolutionary relationships of the pregnancy-associated glycoproteins, an aspartic proteinase subfamily consisting of many trophoblast-expressed genes," <i>Proc. Natl. Acad. Sci., USA</i> , 94:12809-12816, 1997.
	C42	Xie <i>et al.</i> , "The gene encoding bovine pregnancy-associated glycoprotein-1, an inactive member of the aspartic proteinase family,,: Gene, 159:193-197, 1995.
	C43	Xie <i>et al.</i> , "Trophoblast-specific processing ans phosphorylation of pregnancy-associated glycoprotein-1 in day 15 to 25 sheep placenta," <i>Biol. Reprod.</i> , 54:122-129, 1996.
	C44	Zoli <i>et al.</i> , "Light and electron microscopic immunolocalizationof bicine pregnancy-associated glycoprotein in the bovine placentome," <i>Biol. Reprod.</i> , 46:623-629, 1992.
	C45	Zoli <i>et al.</i> , "Purification and characterization of a bovine pregnancy-associated glycoprotein," <i>Biol. Reprod.</i> , 45:1-10, 1991.
	C46	Zoli <i>et al.</i> , "Radioimmunoassay of a bocine pregnancy-associated glycoprotein in serum: its application for pregnancy diagnosis," <i>Biol. Reprod.</i> , 46:83-92, 1992.

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